

Two-piece ALIF cage optimizes the bone–implant interface in a 360° setting

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Abstract

Introduction Clinical research has documented that cage subsidence and the loss of balance correction is a significant complication related to spinal fusion. Subsidence is a multifactorial complication, where implant design is one important element. The aim of the study is to compare the rigidity and bone–implant relative motion of segments treated with either a conventional one-piece ALIF cage versus a two-piece ALIF cage, which adapts in situ and permits 7°–21° of lordosis.

Methods Seven lumbosacral (L3–S1) human cadaver specimens were tested in a universal spine tester in the intact condition, the specimens instrumented with a two-piece ALIF cage (Statur[®]-L, FBC Device, Denmark) and a one-piece ALIF cage (Pezo[™]-A, Ulrich GmbH & Co. KG., Germany), both supplemented with a pedicle screw system using pure moments of ± 7.5 Nm in three principal motion directions. For assessment of the bone–implant interface, fluoroscopic videos were captured during motion and 3D motion was measured using an optical motion capturing system.

Results Significantly less motion at the implant–endplate interface was found for the two-piece cage ($1.0^\circ \pm 0.6^\circ$) in comparison to the one-piece cage ($4.2^\circ \pm 1.7^\circ$) in flexion/extension. No significant differences in segment rigidity

were found between the one-piece and two-piece cages in the 360° setup, while both configurations significantly reduced the range of motion compared to the intact condition ($p < 0.05$).

Conclusion In comparison to the traditional one-piece ALIF cages, the two-piece cage concept reduced the relative motion at the bone–implant interface without compromising stability.

Keywords In vitro · Biomechanics · Lumbar spine · ALIF · Sagittal balance

Introduction

Spinal fusion has been the gold standard until the advent of motion sparing technologies, i.e., the total disc arthroplasty, which were first introduced in the mid 1980s [1–4]. Clinical fusion studies indicate that standard lordotic interbody cages seldom improve the patient’s sagittal balance, but generally, they improve the disc height and fusion rate [5–7]. Disc arthroplasty was introduced as an alternative to fusion and to prevent possible known complications following lumbar fusion. The technology has been found to allow for a more physiological spinal alignment and improve bone–implant interface during the initial loading and healing phase [8–11]. These two factors have been found important for successful clinical outcome and for avoiding late complications (implant subsidence, loss of lordosis correction, and adjacent disc degeneration) [4, 12, 13].

The concept of a two-piece ALIF fusion device is generated from a study indicating that the early stage disc arthroplasty implants, intended to move forever but ‘mistakenly’ ended up fusing, ironically, had superior outcomes in comparison to ‘successful’ non-fusion implants [14]. An

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hypothesis for these findings could be that the degenerated spine benefits from allowing alignment adjustment, meaning better alignment between implant footprint and vertebral endplates; combined with the fact that lumbar degenerated spines quite often auto-fuse [7, 15].

The aim of the present study is to compare the bone–implant relative motion and rigidity of two conceptual different cage designs, a two-piece ALIF cage versus a traditional one-piece ALIF cage in a 360° setting.

Materials and methods

In a human lumbar cadaver model, we analyzed the segmental relative motion and its impact on the implant–endplate interface, using two different ALIF implant concepts; the two-piece ALIF cage (Statur®-L, FBC Device ApS, Denmark) and the more commonly used one-piece ALIF cage concept (Pezo™-A, Ulrich GmbH & Co. KG, Germany). Both are commercially available in Europe. The Statur®-L cage is CE-marked with the use of supplemental fixation, (e.g., pedicle screws or anterior plate) and therefore, a pedicle screw test model was used to mimic a

clinical relevant test scenario. Both implants are made of PEEK, have quite similar foot-prints, the same height and surface texture to lock to the endplate. The two-piece ALIF cage (Statur-L) is capable of continuously adapting from 7° to 21° of lordosis in situ, without external adjustment or insertion of additional components. The two-piece technology allows the optimization of segmental lordosis and the cage system will automatically adapt to the supplemental fixation (screws or plate). The two components are placed on top of each other, without any internal locking system (Fig. 1). After insertion, the implant aligns to the vertebral endplates as soon as the inserter is released from the implant (self-adapting). The implant has a keel to avoid anterior–posterior implant migration.

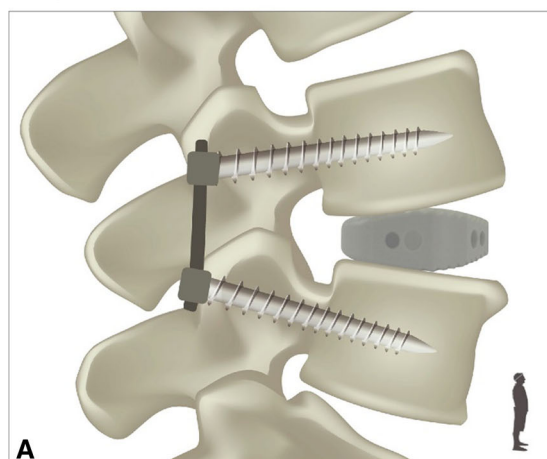
In comparison, the more commonly used one-piece ALIF cage is born with one specific lordosis angle (Fig. 1). A pedicle rod-screw system (tangoRS™, ulrich GmbH & Co. KG, Germany) was added to mimic clinically relevant mechanical circumstances (360° fusion) (Fig. 2).

Seven fresh-frozen human lumbosacral spines (L3–S1) with a median age 55 years (50–56 years) were used for the study. They were obtained from a tissue bank (Anatomy Gifts Registry, Hanover, MC, USA). The study was



Fig. 1 Design of the two tested ALIF cages. Statur-L has a *top* and a *bottom* component with the two elements placed on *top* of each other. The implant has a stabilizing keel on the bone articulating surface. The Pezo implant is a traditional one-piece ALIF cage

One-piece ALIF



Two-piece ALIF

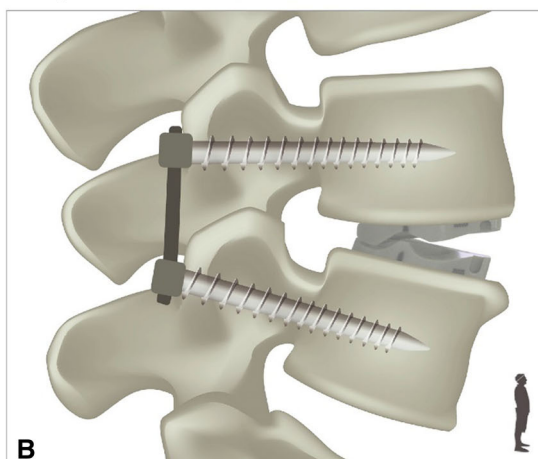


Fig. 2 **a** Illustration of the challenge for a one-piece cage to adapt to different RoM and loadings and thereby keeping a good bone–implant interface. **b** Illustration of the optimized bone–implant interface found

using a two-piece implant. The study documents that a significant RoM takes place also in a 360 fusion model

approved by the ethics committee board of the University of Ulm (Nr. 383/12). The specimens were kept frozen at -20°C and thawed overnight at $+6^{\circ}\text{C}$ before testing. To exclude spinal pathologies, latero-lateral and antero-posterior X-ray films were taken prior to testing. All surrounding soft tissue was dissected, while care was taken to preserve the biomechanically relevant structures. The proximal (L3) and distal (S1) ends of the specimens were embedded in polymethylmethacrylate (PMMA) cement (Technovit 3040, Heraeus Kulzer, Wehrheim, Germany). Special care was taken to align the L4–L5 intervertebral disc horizontally. To mount the specimens in the testing apparatus, flanges were fixed to the PMMA blocks. To prevent desiccation, specimens were sprayed with 0.9% NaCl physiologic solution during testing.

Flexibility testing was performed in a universal spine tester [16] at room temperature. A gimbal fixed to the cranial end of the specimens allows the application of pure bending moments in the three principal motion directions: lateral bending right/left, flexion/extension and axial rotation left/right. During loading, the specimens were allowed to move unconstrained in the remaining five degrees of freedom. The specimens were loaded with pure moments of $\pm 7.5\text{ Nm}$ in all principal motion directions at a loading rate of $1^{\circ}/\text{s}$ (except $0.5^{\circ}/\text{s}$ in axial rotation). The resulting three-dimensional intervertebral motion was captured with an optoelectronic motion analysis system (Vicon MX 13, Vicon, Oxford, UK) (Fig. 3). Following international standards [17], range of motion (RoM) and neutral zone (NZ) were calculated from motion data.

To measure the relative motion between the interbody fusion implants and the adjacent endplates during flexion/extension, a fluoroscope (Exposcop CB7-D, Ziehm,

Nuremberg, Germany) was connected to the spine tester (Fig. 4a). Adapter plates ensured a reproducible positioning of the fluoroscope. Using this approach, the image plane was always exactly perpendicular to the primary motion plane. Video films were taken during the third full motion cycle, and the frames showing the specimen in maximal flexion and extension (turning points) were isolated and used for further analysis. Relative motion was calculated from the fluoroscope images in maximal deflection (Fig. 4b, c) using Photoshop (CS4, Adobe Systems, San Jose, CA, USA). Continuous lines connect the radiographic markers of the interbody implants, while dotted lines represent the endplates. Angles between the upper/lower dotted line (endplate) and upper/lower continuous line (implant) of the respective images were calculated (2 angles at each pair of maximal deflections). The difference in each angle (upper/lower) between the two maximal positions was calculated, and the two differences summed. This sum represents the relative motion between implant and endplate. Care was taken to exactly reproduce the alignment of the lines between the images of the same specimen in maximal deflections, while inaccuracies in the absolute positioning of the anatomical landmark lines were of minor importance due to the calculation of relative changes.

All specimens were tested in the following three conditions (with alternation of 2 and 3):

1. Intact specimen.
2. One-piece ALIF cage (PezoTM-A, Ulrich GmbH & Co. KG, Germany) with pedicle rod-screw system at L4–L5 (tangoRSTM, Ulrich GmbH & Co. KG, Germany) (One-Piece).

Fig. 3 Specimen equipped with retroreflective markers mounted in the spine tester (center). Six infrared cameras are arranged circumferentially to capture the three-dimensional motion of the spine



3. Two-piece ALIF cage (Statur[®]-L, FBC Device ApS, Denmark) with pedicle rod-screw system at L4-L5 (tangoRS[™], ulrich GmbH & Co. KG, Germany) (Two-piece).

The intact condition served as control for all subsequent steps.

The implantations were carried out according to the manufacturers' guidelines by an experienced surgeon. Adequate implant size was chosen individually to ensure good performance of the implants.

For the anterior fusion procedures, the intervertebral disc space was prepared with a subtotal anterior discectomy, which consisted of removal of the entire nucleus pulposus and cartilaginous endplates with pituitary rongeurs and curettes, leaving the lateral and posterior aspect of the annulus fibrosus intact. The ALIF cages were chosen slightly higher than the disc space following the distraction–compression principle. The Pezo[™]-A was chosen as benchmark because it provides a foot-print comparable to the Statur[®]-L device. This allows testing the implants in an alternating order without compromising performance. Pedicle screw entry points were prepared with an awl. The self-tapping screws were inserted without pilot holes and rigidly connected with titanium rods and locking screws.

Data were analyzed using statistics software (SPSS 19, SPSS Inc., Chicago, IL, USA). After testing for normal distribution (Shapiro–Wilk test), a one-way analysis of variance (ANOVA) with Tukey post hoc test for

intervertebral motion data (RoM) and a two-sided Student's *t* test for relative motion data was performed to check for significant differences. The significance level was set to $\alpha = 0.05$.

Results

Significantly less motion at the implant–endplate interface was found for the two-piece device ($1.0^\circ \pm 0.6^\circ$) in comparison to the one-piece ALIF cage ($4.2^\circ \pm 1.7^\circ$) in flexion/extension (Fig. 5). At the same time, no statistically significant differences were found in the overall segmental RoM between the one-piece or two-piece ALIF cage in the 360° set-up, i.e., $3.5^\circ \pm 1.9^\circ$ for the one-piece and $4.2^\circ \pm 1.8^\circ$ for the two-piece ALIF in flexion/extension. Both configurations significantly reduced the RoM in flexion/extension, lateral bending and axial rotation compared to the intact condition in a 360° setup ($p < 0.05$) (Fig. 6).

Discussion

The two-piece ALIF cage significantly reduced the relative motion at the bone–implant interface without compromising stability. This means that with this two-piece self-adapting cage technology, an unchanged mechanical bone–implant interface could be measured in the total range of

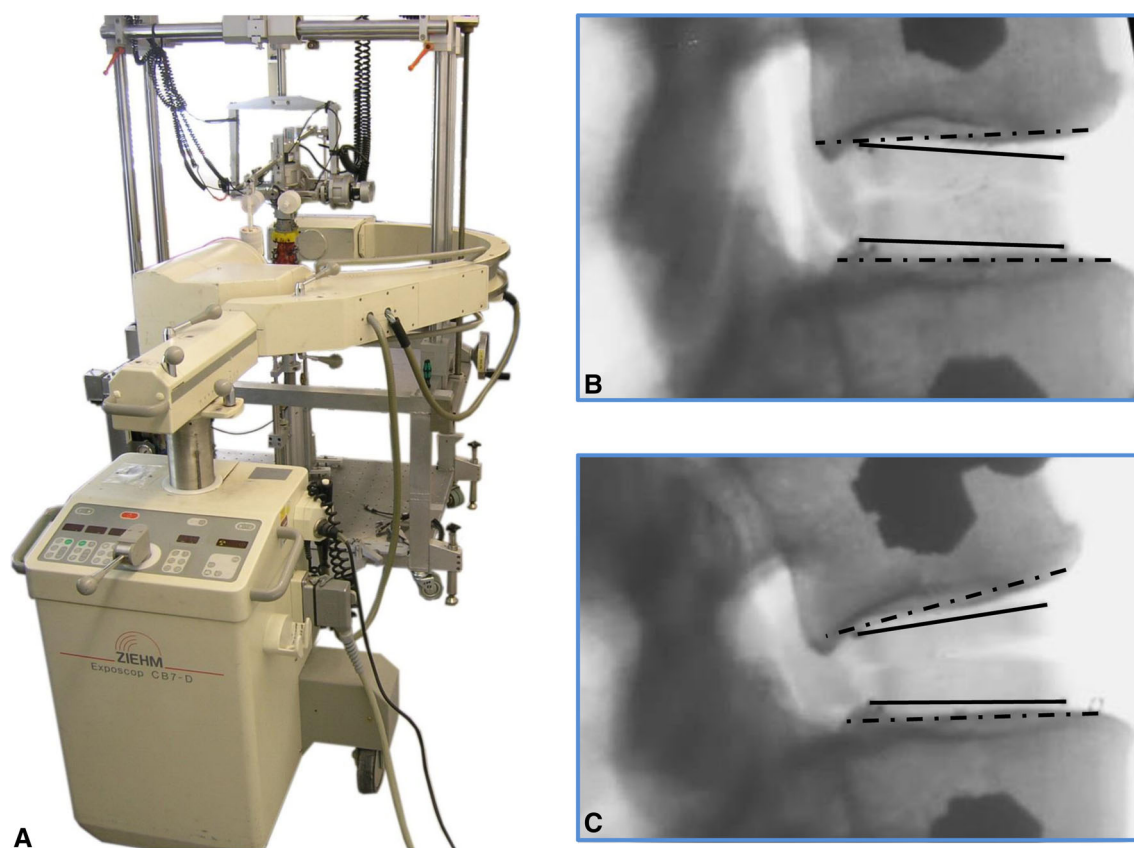


Fig. 4 **a** Fluoroscope affixed to the spine tester; **b** fluoroscope image of the segment instrumented with the Statur®-L implant in maximal flexion; **c** fluoroscope image of the treated segment instrumented with the same implant in maximal extension. *Dotted lines* are drawn

parallel to the endplates, while *continuous lines* connect the X-ray markers of the implant. Since this cage consists of two components, it can follow the movement of the vertebral endplates

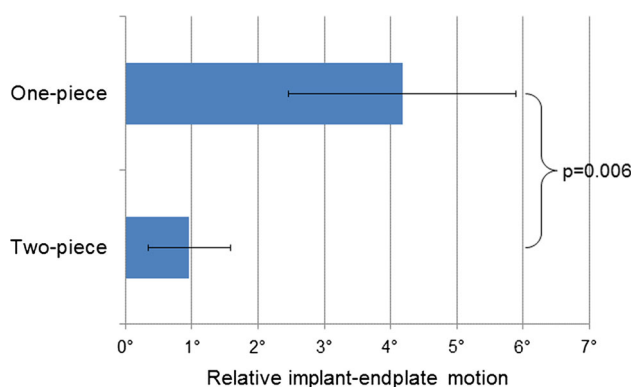


Fig. 5 The relative motion between implant and endplate of the treated segment for the one-piece and the two-piece implant in flexion/extension

flexion–extension. In comparison, the one-piece cage lost anterior cage–endplate contact when the spine moved into extension. The one-piece cage consequently ends up having a total implant load bearing at the posterior part of the implant which could result in a “stone-in-the-shoe” phenomenon [14]. This is an expected scenario when a patient stands and the spine is relatively extended.

Expandable cage technology is a recent innovation and an increasingly popular alternative to one-piece cages. Some of the implants are relatively complex in their design, and complication data are still limited [18–20]. The biomechanical behavior of the tested two-piece, self-adapting ALIF cage appears to be different than multi-piece cages that expand, though the measurements used differs between the studies. As the height of the multi-piece expandable cages is increased, the lordotic angulation of the expandable implants has an impact on the contact force and the location of the center of pressure and can induce significant stress concentration at the endplates [18]. In contrast, the two-piece, self-adapting ALIF cage does not change in overall height. Therefore, we would not expect a stress-concentration effect at the endplates. The lack of relative motion between implant and endplate found in the current study supports this statement. However, direct measurement of pressure under both types of cages would be required to confirm this.

The biomechanical bone–implant interface, has been shown to be of importance for the load sharing and stress distribution, which again is stated to have an impact on

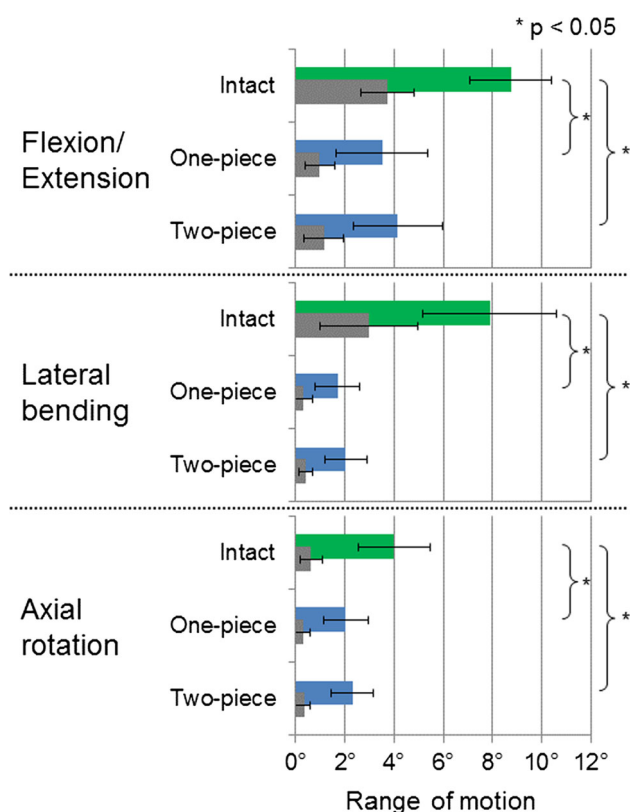


Fig. 6 Range of motion and neutral zone (gray bars) of the two implants in comparison to the intact state in the three principal motion planes

subsidence and thereby loss of the intended correction (segmental alignment and height) [21]. When taking the above into account, it is important to note that the two-piece device did not increase the overall segmental flexibility when used with supplemental instrumentation. The one-piece implant and two-piece implants did not show significantly different segmental movement; but in the two-piece group, the minor movement is taking place within the implant pieces and in the one-piece group between endplate and implant. The current study has some limitations common for biomechanical in vitro experiments. First, the results represent only the immediate postoperative stability of the various implant configurations and do not include the effects of tissue remodeling or long-term viscoelastic response. It is important to keep in mind that cage subsidence is a multifactorial complication involving endplate preparation, strength of additional instrumentation (screws or plates), choice of bone graft material, bone quality etc. Additionally, the physiological loads in the lumbar spine are still not completely known. It was therefore decided to apply pure bending moments, so that the load applied to the specimen was constant along the length of the specimen. This loading scheme was chosen according to the recommendations of Wilke et al. [17] and is thought to

approximate estimated daily in vivo peak torques [22], but is low enough not to damage the cadaveric motion segment.

Conclusion

In comparison to the traditional one-piece ALIF cages, the two-piece ALIF cage concept reduced the relative motion at the bone–implant interface without compromising stability. Clinical studies are needed before concluding on the potential benefits related to this new two-piece self-adapting fusion technology.

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Compliance with ethical standards

Conflict of interest None.

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References

- Christensen FB, Hansen ES, Eiskjaer SP, Hoy K, Helmig P, Neumann P, Niedermann B, Bunger CE (2002) Circumferential lumbar spinal fusion with Brantigan cage versus posterolateral fusion with titanium Cotrel-Dubousset instrumentation: a prospective, randomized clinical study of 146 patients. *Spine (Phila Pa 1976)* 27:2674–2683
- Siepe CJ, Heider F, Wiechert K, Hitzl W, Ishak B, Mayer MH (2014) Mid- to long-term results of total lumbar disc replacement: a prospective analysis with 5- to 10-year follow-up. *Spine J* 14:1417–1431
- Szpalski M, Gunzburg R, Mayer M (2002) Spine arthroplasty: a historical review. *Eur Spine J* 11(Suppl 2):S65–S84
- van den Eerenbeemt KD, Ostelo RW, van Royen BJ, Peul WC, van Tulder MW (2010) Total disc replacement surgery for symptomatic degenerative lumbar disc disease: a systematic review of the literature. *Eur Spine J* 19:1262–1280
- Schroeder GD, Kepler CK, Millhouse PW, Fleischman AN, Maltenfort MG, Bateman DK, Vaccaro AR (2016) L5/S1 fusion rates in degenerative spine surgery: a systematic review comparing ALIF, TLIF, and axial interbody arthrodesis. *Clin Spine Surg* 29:150–155
- Videbaek TS, Bunger CE, Henriksen M, Neils E, Christensen FB (2011) Sagittal spinal balance after lumbar spinal fusion: the impact of anterior column support results from a randomized clinical trial with an eight- to thirteen-year radiographic follow-up. *Spine (Phila Pa 1976)* 36:183–191
- Pellet N, Aunoble S, Meyrat R, Rigal J, Le Huec JC (2011) Sagittal balance parameters influence indications for lumbar disc arthroplasty or ALIF. *Eur Spine J* 20(Suppl 5):647–662
- Auerbach JD, Jones KJ, Milby AH, Anakwenze OA, Balderston RA (2009) Segmental contribution toward total lumbar range of

- motion in disc replacement and fusions: a comparison of operative and adjacent levels. *Spine (Phila Pa 1976)* 34:2510–2517
9. Chung SS, Lee CS, Kang CS, Kim SH (2006) The effect of lumbar total disc replacement on the spinopelvic alignment and range of motion of the lumbar spine. *J Spinal Disord Tech* 19:307–311
 10. Huang RC, Girardi FP, Cammisa FP Jr, Tropiano P, Marnay T (2003) Long-term flexion-extension range of motion of the pro-disc total disc replacement. *J Spinal Disord Tech* 16:435–440
 11. Frelinghuysen P, Huang RC, Girardi FP, Cammisa FP Jr (2005) Lumbar total disc replacement part I: rationale, biomechanics, and implant types. *Orthop Clin N Am* 36:293–299
 12. Gragnaniello C, Seex KA, Eisermann LG, Claydon MH, Malham GM (2013) Early postoperative dislocation of the anterior Mav-erick lumbar disc prosthesis. *J Neurosurg Spine* 19:191–196
 13. Guyer RD, McAfee PC, Banco RJ, Bitan FD, Cappuccino A, Geisler FH, Hochschuler SH, Holt RT, Jenis LG, Majd ME, Regan JJ, Tromanhauser SG, Wong DC, Blumenthal SL (2009) Prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of lumbar total disc replacement with the CHARITE artificial disc versus lumbar fusion: five-year follow-up. *Spine J* 9:374–386
 14. Putzier M, Funk JF, Schneider SV, Gross C, Tohtz SW, Khodadadyan-Klostermann C, Perka C, Kandziora F (2006) Charite total disc replacement—clinical and radiographical results after an average follow-up of 17 years. *Eur Spine J* 15:183–195
 15. Huang KT, Adogwa O, Babu R, Lad SP, Bagley CA, Gottfried ON (2014) Radiological evidence of spontaneous spinal arthrodesis in patients with lower lumbar spondylolisthesis. *Spine (Phila Pa 1976)* 39:656–663
 16. Wilke HJ, Claes L, Schmitt H, Wolf S (1994) A universal spine tester for in vitro experiments with muscle force simulation. *Eur Spine J* 3:91–97
 17. Wilke HJ, Wenger K, Claes L (1998) Testing criteria for spinal implants: recommendations for the standardization of in vitro stability testing of spinal implants. *Eur Spine J* 7:148–154
 18. Pekmezci M, Tang JA, Cheng L, Modak A, McClellan RT, Buckley JM, Ames CP (2016) Comparison of expandable and fixed interbody cages in a human cadaver corpectomy model: fatigue characteristics. *Clin Spine Surg* 29:387–393
 19. Stein IC, Than KD, Chen KS, Wang AC, Park P (2015) Failure of a polyether-ether-ketone expandable interbody cage following transforaminal lumbar interbody fusion. *Eur Spine J* 24(Suppl 4):S555–S559
 20. Coe JD, Zucherman JF, Kucharzyk DW, Poelstra KA, Miller LE, Kunwar S (2016) Multiexpandable cage for minimally invasive posterior lumbar interbody fusion. *Med Devices (Auckl)* 9:341–347
 21. Tan JS, Bailey CS, Dvorak MF, Fisher CG, Oxland TR (2005) Interbody device shape and size are important to strengthen the vertebra-implant interface. *Spine (Phila Pa 1976)* 30:638–644
 22. Adams MA, Hutton WC (1981) The relevance of torsion to the mechanical derangement of the lumbar spine. *Spine (Phila Pa 1976)* 6:241–248